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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,017	01/14/2004	Heinrich Kladders	1/1448	3319
28501	7590	07/13/2007	EXAMINER	
MICHAEL P. MORRIS			PATEL, NIHIL B	
BOEHRINGER INGELHEIM CORPORATION			ART UNIT	PAPER NUMBER
900 RIDGEURY ROAD				3772
P. O. BOX 368				
RIDGEFIELD, CT 06877-0368				
MAIL DATE		DELIVERY MODE		
07/13/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/757,017	KLADDERS ET AL.	
	Examiner	Art Unit	
	Nihir Patel	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05.01.2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-8 and 10-20 is/are rejected.
 7) Claim(s) 9 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 04.27.2007 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed April 27th, 2007 have been fully considered but they are not persuasive. The applicant argues that the WO 97/12687 reference does not disclose microstructures and nanostructures located on the surface(s). The examiner disagrees. First the examiner would like to point out that claims 1, 7, 9, 10, 16 and 18 clearly state that **at least one of** microstructures and nanostructures, implying that either 1 or both, microstructures or nanostructures is required. The WO 97/12687 reference clearly states a microstructures located on the surfaces (**see page 9 beginning last paragraph continued on page 10**).

The applicant also argues that the microstructures of '143 is disclosed to produce the actual apertures and orifices that make up the channels 15, filter 13 and ports 14 not nozzle as claimed. The examiner disagrees with the applicant's arguments. The last two paragraphs on page 9 of the WO 97/12687 clearly states that the nozzle in the nozzle member is preferably micro-structured.

Terminal Disclaimer

2. The terminal disclaimer filed on April 27th, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/982,991 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Drawings

3. The drawings were received on April 27th, 2007. These drawings are accepted.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-8 and 10-15** are rejected under 35 U.S.C. 102(b) as being anticipated by Jaeger et al. (WO 97/12687).

6. **As to claims 1 and 12**, Jaeger teaches a device of miniaturized construction for producing high pressure in a fluid to be atomized that comprises a nozzle **54** for a delivery device for fluids comprising an inlet side and an outlet side wherein the outer surface of the outlet side includes at least one of microstructures and nanostructures (see page 9 beginning last paragraph continued on page 10).

7. **As to claim 2**, Jaeger teaches an apparatus that comprises at least one nozzle opening (see page 9 last paragraph).

8. **As to claim 3**, Jaeger teaches an apparatus that comprises at least two nozzle openings oriented so that the jets of fluid emerging from them intersect (**In a nozzle member having at least two nozzle openings at the outlet end, the directions of spray may be inclined relative to one another at an angle from 20 to 160 degrees, preferably at an angle 60 to 150 degrees. The directions of spraying meet in the vicinity of the nozzle openings**” (see page 10 first full paragraph). This implies that the jets of fluid would intersect).

9. **As to claim 4**, Jaeger teaches an apparatus wherein the nozzle is formed from at least two constructional units (**The nozzle member consists of two plates of glass and/or silicon firmly**

Art Unit: 3772

joined together (see page 9 fourth paragraph). Each plate of glass being a constructional unit makes it two constructional units).

10. **As to claim 5,** Jaeger teaches an apparatus wherein the constructional units comprise superimposed plates, at least one of the plates produced by microtechnology, so that the plates lying one on top of the other define, on one side, a fluid inlet connected to a channel system and/or a filter system which then opens into one or more fluid outlets (**see page 9 fourth paragraph).**

This is a product-by-process where the product is the superimposed plates lying one on top of the other define, on one side, a fluid inlet connected to a channel system and/or a filter system which then opens into one or more fluid outlets. The process or method of production is microtechnology.

Even though product-by-process claims are limited by and defined by the process, determination or patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 777 F.2d. 695, 227 USPQ 964, 966 (Fed. Cir. 1985).

11. **As to claim 6,** Jaeger teaches an apparatus wherein the nozzle has at least two nozzle outlets oriented towards one another (**see page 10 first full paragraph).**

12. **As to claim 7,** Jaeger teaches a device of miniaturized construction for producing high pressure in a fluid to be atomized that comprises a nozzle 54 having one or more nozzle openings and an outer surface at a fluid outlet side of the nozzle (**see page 9 beginning last paragraph**

continued on page 10); a nozzle holder 53 which comprises a through-bore having a sidewall initiating at a position in communication with the one or more nozzle openings of the fluid outlet side of the nozzle, and terminating at an end face of the nozzle holder; wherein at least one of the following surfaces includes at least one of microstructures and nanostructures (see page 9 beginning last paragraph continued on page 10): the outer surface of the fluid outlet side of the nozzle, an outer surface of the end face of the nozzle holder, or the side wall of the through-bore of the nozzle holder.

13. **As to claim 8,** Jaeger teaches an apparatus wherein the through-bore 7 of the nozzle holder 53 widens out 33 from one or more nozzle openings to the end face thereof (see figure 1).

14. **As to claim 10,** Jaeger teaches an apparatus wherein a side of the through bore 7 that is remote from the one or more nozzle openings includes at least one of microstructures and nanostructures (see page 9 beginning last paragraph continued on page 10).

15. **As to claim 11,** Jaeger teaches an apparatus wherein the nozzle comprises an outlet side and an inlet side (see page 9 beginning last paragraph continued on page 10).

16. **As to claim 13,** Jaeger teaches an apparatus that comprises a nozzle system (see figure 1).

17. **As to claim 14,** Jaeger teaches an apparatus that comprises a lower 70 and upper 51 housing part mounted to be rotatable relative to one another, the upper part of the housing containing a spring housing 67 with a spring 68 which is tensioned by rotating the two housing parts by means of a locking clamping mechanism 62 and is released by pressing a release button 64 on the upper part of the housing, the spring moving a power take-off flange 56 connected to a piston 57 on the lower end of which a container can be fitted, and at the upper end of which are

Art Unit: 3772

found a valve **58** and a pressure chamber **4** which is connected for fluid transmission to the nozzle system formed in the upwardly open part of the upper housing part (**see page 17 paragraph 4**).

18. **As to claim 15**, Jaeger teaches an apparatus wherein the device is an inhaler atomizer for delivering medicinal or pharmaceutical fluids (**see page 3 paragraph 1**).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claims **16-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaeger et al (WO 97/12687) in view of Waldrum (5,823,436).

22. **As to claim 16**, Jaeger substantially discloses the invention as claimed, see rejection to claim 1 and 12 above; however, Jaeger does not expressly disclose surface structure elevations and/or depressions with a height/depth of 0.1 to 100 microns at least on one of the following surfaces: the outer surface of the liquid outlet side of the nozzle, the outer surface of the end face

of the nozzle holder, the side wall of the bore or hole of the nozzle holder, the outer surface of the end face of the check nut, or the side wall of the bore or hole of the check nut. The examiner selected the outer surface of the liquid outlet side of the nozzle, which Jaeger has disclosed. However, Waldrum teaches that the spacing (i.e. height) between the elevations and depressions are in the range of from 0.1 to 200 microns (**Abstract**). “For example, the downward jets can be emitted through grooves of 0.005 inch, the upward jets through grooves of 0.015 inch, and the central jets through grooves of 0.010 inch” (**column 7, lines 1-4**). As seen in **Figure 2**, the grooves **36** are located on top of outlet orifice **34** of the nozzle body **22**, so that would be the outer surface of the liquid outlet side of the nozzle. Waldrum further teaches that “in order to improve the evenness of application, it is possible to vary either or both of the density and the size of the grooves in order to reduce this effect” (**column 6, lines 61-63**). In addition “grooves **36** form a line **72** of orifices **34** for emission of the fluid in a fan shaped spray pattern **74**” (**column 5, lines 3-5**). Therefore, it would have been obvious, to one of ordinary skill in the art at the time of the invention, to modify the outer surface of the liquid outlet side of the nozzle of Jaeger so that it includes grooves, or elevations and/or depressions on the surface structure as taught by Waldrum in order to emit uniform droplet sizes from 0.1 to 100 microns in size because doing so would provide an evenness of the application of the spray as taught by Waldrum.

23. **As to claim 17**, Waldrum teaches wherein the spacings between the elevations and depressions are in the range from 0.1 to 200 microns. “One or both of the nozzle plug and the nozzle body have a plurality of narrow grooves (**or elevations and/or depressions on the**

Art Unit: 3772

surface structure). This dimension of 0.001 to 0.015 inch is uquivalent to 25 to 400 microns in width and therefore covers the claimed range (**Abstract**).

24. **As to claim 18,** the production by microtechnology/nanotechnology is a product-by-process limitation. As shown in **Figure 2**, the grooves **36** of Waldrum appear to account for at least 20%, more than likely much more, of the corresponding surface.

25. **As to claim 19,** the production by microtechnology/nanotechnology is a product-by-process limitation. As shown in **Figure 2**, the grooves **36** of Waldrum appear to account for at least 20%, more than likely much more, of the corresponding surface.

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted).

26. **As to claim 20,** Jaeger/Waldrum teach elevations/depressions as shown in the rejection of claims 16 and 17. This is a product by process claim where the product is the elevations/depressions and the process is producing the said elevations/depressions by subtractive or additive treatment of the surfaces, the treatment selected from stamping, etching, laser ablation, galvanic machining, adhesively attaching a structured film, adhesion of a powder, spraying with suspensions and depositing sublimates.

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does

not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted).

Allowable Subject Matter

27. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose a check nut engaging the nozzle holder and having an end face and a bore including a side-wall thereof which communicates with the through bore of the nozzle holder and widens out continuously therefrom.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300..

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 3772



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7/9/07